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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/640,737	08/17/00	MANDELKOW E	28384/36668

HM12/0214

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EXAMINER	
DUFFY, P	
ART UNIT	**PAPER NUMBER**
1645	6

DATE MAILED: 02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/640,737	Mandel Kaw et al.
Examiner	**Group Art Unit**
DUFFY	1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ~~three~~ one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 5, 6, 7, 8, 10, 11, 12, 13, 15-22 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 5, 6, 7, 8, 10, 11, 12, 13, 15-22 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Other Sequence compliance - claims.

Office Action Summary

Election/Restriction

1. Claims 17-21 are objected to as reciting improper Markush Groups. M.P.E.P. 803.02 states that: Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 12 and 13, drawn to a combination of epitopes on tau protein for use in a method of treatment of Alzheimer's Disease, classified in Class 530, subclass 300+ and Class 514, subclass 2 .

Group II. Claims 5-8, drawn to a protein kinase of a molecular weight of 70 KDa made by particular process (i.e. product by process claims), classified in Class 530, subclass 350.

Group III. Claims 10-11, and 22 drawn to a method of using a protein kinase to convert tau to Alzheimer's tau protein, classified in Class 435, subclass 68.1.

Specie A - a protein kinase as defined by claim 3.

Specie B - a protein kinase as defined by claim 4.

Specie C - glycogen synthase kinase -3.

Specie D - cdk2-cyclin A.

Specie E - MAP kinase.

Group IV. Claims 15 and 16, drawn to an antibody which binds a protein kinase having a molecular weight of 70 kDa, classified in Class 530, subclass 387.1.

Group V. Claims 17-21, drawn to methods of diagnosis of Alzheimer's Disease and compositions therefore by the detection of phosphorylated tau epitopes, classified in Class 435, subclasses 7.1, 15, and 21.

Group VI. Claims 17-21, drawn to methods of diagnosis of Alzheimer's Disease and compositions therefore by the detection of a protein kinase wherein the protein kinase is defined by claim 3, classified in Class 435, subclasses 7.1, 15, and 21.

Group VII. Claims 17-21, drawn to methods of diagnosis of Alzheimer's Disease and compositions therefore by detection of a protein kinase wherein the protein kinase is defined by claim 4, classified in Class 435, subclasses 7.1, 15, and 21.

Group VIII. Claims 17-21, drawn to methods of diagnosis of Alzheimer's Disease and compositions therefore by the detection of a protein kinase wherein the protein kinase is glycogen synthase kinase -3, classified in Class 435, subclasses 7.1, 15, and 21.

Group IX. Claims 17-21, drawn to methods of diagnosis of Alzheimer's Disease and compositions therefore by the detection of a protein kinase wherein the

protein kinase is cdk2-cyclin A, classified in Class 435, subclasses 7.1, 15, and 21.

Group X. Claims 17-21, drawn to methods of diagnosis of Alzheimer's Disease and compositions therefore by the detection of a protein kinase wherein the protein kinase is MAP kinase, classified in Class 435, subclasses 7.1, 15, and 21.

Group XI. Claims 17-21, drawn to methods of diagnosis of Alzheimer's Disease and compositions therefore by the detection of phosphatase wherein the phosphatase is phosphatase PP2a, classified in Class 435, subclasses 7.1, 15, and 21.

Group XII. Claims 17-21, drawn to methods of diagnosis of Alzheimer's Disease and compositions therefore by the detection of phosphatase wherein the phosphatase is phosphatase PP1, classified in Class 435, subclasses 7.1, 15, and 21.

Group XIII. Claims 17-21, drawn to methods of diagnosis of Alzheimer's Disease and compositions therefore by the detection of phosphatase wherein the phosphatase is calcineurin, classified in Class 435, subclasses 7.1, 15, and 21.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions I, II, and IV are related as products. These products are separate and distinct each from the other because they have different chemical structures, perform different biological functions(structural versus enzymatic versus binding), and are found in different biological locations (blood plasma versus intracellular). For example, the tau epitopes

(Group I) are pieces of the tau protein which is known to lack enzymatic activity, whereas Groups II is a protein kinase as evidenced by their different biochemical characteristics such as molecular weight and pI. Group II and IV are separate and distinct each from the other because the antibodies specifically bind different proteins which perform different biological functions (structural versus enzymatic).

5. Inventions III, and V-XIII are related as methods. The methods of Groups III and V-XIII are separate and distinct each from the other because the methods have different goals, require different method steps and have distinct final outcomes. In the instant case the method of Groups III is the generation of phosphorylated Alzheimer's tau epitopes whereas, the methods of Groups V-XIII are the diagnosis of Alzheimer's disease using separate and distinct agents wherein the agents lack structure and function in common. The methods of Groups III and V-XIII have clearly different final outcomes and method steps and thus are patentably distinct.

6. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Group I is drawn to a combination of tau protein epitopes whereas Group V is drawn to a method of diagnosis by detection of tau protein epitopes. Because the protein epitopes can be used in a materially different process of using that product, such as an immunogen to make an antibody, restriction is proper between the product and processes of using.

7. Inventions II and (III or X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Group II is drawn to a protein kinase of 70 kDa, whereas Groups III or X are drawn to the use of the protein kinase in separate methods (i.e. to make phosphorylated tau protein epitopes or diagnose disease). are separate and distinct methods of making because the method require different method steps which result in different final outcomes (i.e. the isolation of different protein kinases). Because the method steps are different and the proteins can be used in a materially different process such as an immunogen to make an antibody, restriction is proper between the product and processes of using.

8. Inventions IV and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Group IV is drawn to an antibody that binds a protein kinase of 70 kDa, whereas Groups X is drawn to detection of the protein kinase using an antibody for diagnosis of Alzheimer's disease. Because the antibody can be used in a materially different process of use such as immunopurification of the protein, restriction is proper between the product and processes of using.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper and in the absence of restriction would place an undue burden on the examiner.

2/12/01 PAD

search and examination

10. This application contains claims directed to the following patentably distinct species of the claimed invention:

Group III. Claims 10-11, and 22 drawn to a method of using a protein kinase to convert tau to Alzheimer's tau protein, classified in Class 435, subclass 68.1.

Specie A - a protein kinase as defined by claim 3.

Specie B - a protein kinase as defined by claim 4.

Specie C - glycogen synthase kinase -3.

Specie D - cdk2-cyclin a.

Specie E - MAP kinase.

The species are distinct each from the other because they have different chemical structures, perform different biological functions(structural versus enzymatic versus binding), and are found in different biological locations (blood plasma versus intracellular). For the foregoing reasons the species are deemed patentably distinct.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. The following observations are noted for applicants and counsels benefit. The claims contain language (i.e. "use of") which does not place the claims in a statutory category according to US Code. Many claims are improperly dependent upon canceled claims. If applicants elect Group III, the claims will be examined only in light of the elected species. Moreover, some dependent claims are improper in that they are methods which depend from products and visa versa. In order to expedite prosecution, the examiner suggest that applicant reviews the elected claims for compliance with US Code and clarity.

13. Applicant is reminded that claimed sequences, or sequences recited in the claims must be referred to by their SEQ ID NOs as set forth in the MPEP 37 CFR 1.821(d).

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia a. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 6:30 AM to 3:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia a. Duffy, Ph.D.
February 12, 2001

Patricia a. Duffy

Patricia a. Duffy, Ph.D.
Primary Examiner
Group 1600

Application No.: 09/640,737

NOTICE TO COMPLY WI REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Sequence compliance

Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
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